



Providing Safe and Effective Pest
Management Solutions for
Specialty Crop Growers

48741900

IR-4 Headquarters

Rutgers, The State University of New Jersey

500 College Road East, Suite 201 W

Princeton, NJ 08540

732.932.9575

fax: 609.514.2612

ir4.rutgers.edu

February 7, 2012

Ms. Barbara Madden
EPA-OPP-Document Processing (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202

Dear Barbara:

RE: Imidacloprid
Protector 0.5G, EPA Registration No. pending
Protector 2F, EPA Registration No. pending
Imidacloprid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of imidacloprid (1-[6-chloro-3-pyridinyl] methyl)- N -nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid

New Uses:

Description	IR-4 PR No.	Source of New Tolerance
Fish-shellfish, mollusc	10553	Volume 2
Fish	none	Volume 2 and approved waiver request for fish uptake and metabolism study

FEE CATEGORY: R170

REGISTRATION FEE: \$119,952 (See IR-4 Exemption Request below)

Electronic Submission to Follow

The undersigned, Dr. Keith Dorschner, Entomology Program Manager, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers, The State University of New Jersey, Princeton, New Jersey 08540, on behalf of the IR-4 Project and the Agricultural Experiment Station of Washington submits this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, imidacloprid (40 CFR 180.472).

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

List of Studies Submitted in Support of Proposed Tolerances for imidacloprid:

	Vol. No.	Volume Title
48741901	2	Imidacloprid: Magnitude of the Residue on Oyster
48741902	3	IR-4 Minor Use Submission in Support of Tolerances for Imidacloprid In or On Fish and Shellfish (note: this is a volume of non-GLP studies and reports provided to IR-4 in support of the registration)

I request that this petition be reviewed under the Pesticide Registration Improvement Act and that EPA should exempt the registration fee for review of these uses.

The toxicological database for imidacloprid is complete, with the exception of an immunotoxicity study. The toxicology database for imidacloprid does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system.

An immunotoxicity study is required as a part of new data requirements in 40 CFR Part 158 for conventional pesticide registration; however, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently used for overall risk assessment. Therefore, a database uncertainty factor (UFDB) is not needed to account for lack of this study. EPA has determined that reliable data show the safety of infants and children would be adequately protected with a 1X FQPA SF for all exposure scenarios, except acute dietary (all populations).

A developmental neurotoxicity study was performed with imidacloprid and well-defined NOAELs were achieved in the study.

A fish uptake and metabolism study has not been performed for imidacloprid; however, a waiver has been submitted to EPA and approved. See Volume 3 for the waiver rationale. ChemSAC approval of the waiver is provided in Section G of the petition (Volume 1). A tolerance on fish is proposed in Section F of the petition. EPA may consider this tolerance request appropriate if there are concerns about inadvertent residues in fish as a result of oyster bed treatments.

I also submit the following in support of the proposed tolerances for imidacloprid:

1. Notice of Filing
2. EPA Form 8570-1 (Protector 0.5G)
3. EPA Form 8570-1 (Protector 2F)
4. EPA Form 8570-27 (Mallet 0.5G)
5. EPA Form 8570-27 (Imidacloprid 2F Insecticide/Nuprid 2SC)
6. EPA Form 8570-34 (Protector 0.5G)
7. EPA Form 8570-34 (Protector 2F)
8. EPA Form 8570-35 (Protector 0.5G) Agency and Public copies
9. EPA Form 8570-35 (Protector 2F) Agency and Public copies
10. Protector 2F draft label (5 copies)
11. Protector 0.5G draft label (5 copies)

The following non-GLP studies were provided to IR-4 in support of the registration. They are found in Volume 3.

1. Experimental Applications of Imidacloprid to Control Burrowing Shrimp at the Commercial Scale: 2008
2. Field Trials of Imidacloprid on Burrowing Shrimp, 2009
3. Rationale for Waiving the Need for a Fish Uptake and Metabolism Study
4. Toxicological Evaluation of Imidacloprid (as Imida E AG 2F) using Sheepshead Minnows
5. Assessing the Hazards of Imidacloprid to Non-Target Fishes
6. Development of a new method for the determination of residues of the neonicotinoid insecticide Imidacloprid in juvenile Chinook (*Oncorhynchus tshawytscha*) using ELISA detection
7. Final Report – December 2011 Non-Target Effects of Imidacloprid on Dungeness crab in Willapa Bay, Washington 2008 to 2011
8. Impact of imidacloprid on epi-benthic and benthic invertebrates: Initial studies to describe the Sediment Impact Zone (SIZ) related to imidacloprid treatments to manage burrowing shrimp
9. Impact of imidacloprid on epi-benthic and benthic invertebrates: Preliminary small plot studies, 2006-07
10. Studies on the non-target effects of imidacloprid on Dungeness crab in Willapa Bay, Washington
11. SUPPLEMENT Toxicological Evaluation of Imidacloprid (as Imida E AG 2F) Using Sheepshead Minnows – Draft Report submitted by Nautilus Environmental, LLC to the University of Washington
12. Ecological Risk Assessment of Imidacloprid Applications to Control Burrowing Shrimp in Oyster Beds of Willapa Bay and Grays Harbor, WA

Yours very truly,
Interregional Research Project No. 4
Petitioner

Per 

Keith Dorschner, Ph.D.
Entomology Program Manager
Rutgers, the State University of NJ
500 College Road East, Suite 201 W
Princeton, NJ 08540

cc: Alan Schreiber
RFC (transmittal letter, petition)